for patients who do not respond to traditional disease modifying anti-rheumatic drugs (DMARDs). This study aimed to compare the efficacy of biological agents with traditional DMARDs for methotrexate (MTX) treatment failure patients. **METHODS:** Four DMARDs (hydroxychloroquine, sulfasalazine, methotrexate, leflunomide) and five anti-TNF drugs (adalimumab, etanercept, golimumab, infliximab, certolizumab) were selected according to expert consensus. A systematic search of the published systematic reviews was performed including MEDLINE, EMBASE and Cochrane Library. Among the identified 52 systematic reviews, 3 systematic reviews were finally selected and updated to July 2013. Data extraction and methodological quality assessment using Cochrane Risk of Bias was performed in pairs. Comparative efficacy was analyzed using Baysian mixed treatment comparison (MTC). **RESULTS:** A total of 85 trials from 7,938 citations were included. Nineteen trials were grouped as MTX failure patients (mean age: 52.9 years, mean of rheumatoid factor positive rate: 76.6%). Nine studies were included in the analysis of Health Assessment Questionnaire (HAQ). The best treatment was certolizumab combined with MTX (MD -0.40,95% CrI -0.95 to 0.13). For comparative effects on DAS 28-ESR <2.6 (remission), 4 trials were included in analysis. The best treatment was golimumab combined with MTX (OR 24.5, 95% CrI 3.51 to 99.52). For comparative effects on ACR 70, the best treatment was certolizumab combination with MTX (OR 10.46, 95% CrI 3.66 to 24.41) in 11 trials. **CONCLUSIONS:** In the MTX failure patients, certolizumab combination with MTX lowered HAQ score than MTX. The result of DAS 28- ESR<2.6 (remission), golimumab combined with MTX was the most effective treatment. Certolizumab combined with MTX was best treatment for the ACR 70 response.

### PMS8

### QUALITY OF LIFE ASSESSMENTS IN KOREAN PATIENTS WITH RHEUMATOID ARTHRITIS (RA): AN ANALYSIS FROM THE PHASE III TRIAL TO EVALUATE EQUIVALENCE OF THE ETANERCEPT BIOSIMILAR HD203 AND ENBREL® IN COMBINATION WITH METHOTREXATE (MTX) IN PATIENTS WITH RA; THE HERA STUDY

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**OBJECTIVES:** Quality of Life (QoL) is important for patients with RA and Enbrel® has demonstrated QoL benefits in this patient group. HD203 is an etanercept biosimilar, which reported pharmacokinetic bioequivalence to the reference product Enbrel® in a Phase I trial and, more recently, demonstrated equivalent efficacy and comparable safety in a phase III randomized trial in Korean patients with RA. Assessing QoL was a secondary objective of the HERA study, the results of which are reported here. **METHODS:** Patients (male or female aged ≥20 years) with active RA were randomized (1: 1) to 25 mg HD203 or Enbrel®, administered subcutaneously twice weekly with MTX for 48 weeks. QoL assessments (Short Form 36, SF-36; Functional Assessment of Chronic Illness Therapy-Fatigue, FACIT-F; EuroQol-5 dimension, EQ5D) were undertaken at weeks 24 and 48. **RESULTS:** In total, 294 patients were randomized (147 to HD203; 147 to Enbrel®). There was no significant difference between groups on QoL assessments at baseline. QoL assessments were similar for HD203 and Enbrel® at week 24 and 48 overall. However, SF-36 Role Emotional and Bodily Pain subscales showed significant increase in favour of HD203 at week 24 (p=0.0252) and week 48 (p=0.0243) respectively. No significant difference was observed between HD203 and Enbrel® for FACIT-F scores at week 24 or 48, except at week 48 for the Emotional Well-being domain, which was significantly improved with Enbrel® vs. HD203 (p=0.0360). No significant differences between groups in EQ5D scores were observed at any time. **CONCLUSIONS:** Together with previous reports of equivalent pharmacokinetics and efficacy, and comparable safety, these data support the biosimilarity of HD203 vs. Enbrel®.

### PMS9

### COMPARISON OF DISEASE STATUS AND OUTCOMES OF PATIENTS WITH RHEUMATOID ARTHRITIS (RA) RECEIVING ADALIMUMAB OR ETANERCEPT MONOTHERAPY IN EUROPE

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**OBJECTIVES:** To compare the disease status and outcomes of patients with RA receiving adalimumab and etanercept monotherapy in Europe. **METHODS:** A multi-country, multi-center medical chart-review study of RA patients was conducted among rheumatologists in UK/France/Germany/Italy/Spain to collect de-identified data on patients who were recently treated with a biologic as part of usual care. Physicians were screened for duration of practice (3-30 yrs) and patient volume (incl. >5 RA biologic patients/month) and recruited from a large panel to be geographically representative in each country. Eligible patient charts (≥3) were randomly selected from a sample of prospective patients visiting each center/practice during the screening period. Physicians abstracted patient diagnosis, treatment patterns/dynamics and patient symptomatology/disease status/outcomes. Patients on adalimumab/etanercept monotherapy were analyzed. **RESULTS:** 428 eligible RA patient charts were abstracted; 152 on adalimumab (female: 68%, age: 52.1yrs, average months on adalimumab: 22.8, 90% on first biologic) and 142 on etanercept (female: 70%, age: 50.5yrs, average months on etanercept: 24.6, 97% on first biologic). Among patients with available data, latest lab measures documented were (adalimumab vs. etanercept): ESR: 21.0mm/h (range: 16.1 (UK) -24.6 (Germany)) vs. 23.4mm/h (range: 13.5 (France) -29.8 (Italy)), CRP: 9.9mg/dl (range: 5.0 (Italy) -17.0 (Germany)) vs. 13.1mg/dl (range: 7.7 (France) -15.6 (Italy)), rheumatoid factor-positive: 81% (range: 68% (Germany) -86% (Spain)) vs. 85% (range: 62% (Germany) -95% (Spain)), and anti-CPP-positive: 69% (range: 47% (Germany) -83% (France)) vs. 74% (range: 61% (Spain) -83% (France)). Latest disease severity measures documented were (adalimumab vs. etanercept): Swollen Joint Counts: 2.7 (range: 2.2 (Spain) -3.5 (Germany)) vs. 2.6 (range: 0.7 (Spain) -6.3 (UK)), Tender Joint Counts were 3.9 (range: 3.2 (France) -5.1 (Germany)) vs. 3.7 (range: 1.5 (Spain) -7.1 (UK)), Health Assessment Questionnaire (HAQ) rating: 1.6 (range: 0.1 (Spain) -2.3 (Germany)) vs. 1.4 (0.3 (Spain) -2.5 (Germany), DAS28 score: 3.8 (range: 2.5 (UK) -4.8 (Spain)) vs. 3.2 (1.5 (Germany) -6.6 (Spain), VAS score: 3.8 (range: 3.0 (UK) -4.8 (Italy)) vs. 3.1 (range: 1.9 (Germany) -3.9 (Italy)). **CONCLUSIONS:** Among RA patients receiving adalimumab or etanercept monotherapy, disease severity was similar across the EU5, with patients in Spain and France having relatively lower, and patients in Italy, Germany, and UK having relatively higher burden and poorer treatment response. Factors influencing the observed patterns of geographic variation warrant further scrutiny to optimize therapeutic interventions and improve outcomes.

### PMS10

### EFFICACY OF NOVEL DMARDS IN EARLY ACTIVE RHEUMATOID ARTHRITIS: AN INDIRECT COMPARISON

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**OBJECTIVES:** We evaluated the effectiveness of traditional disease-modifying antirheumatic drugs (tDMARDs) and novel DMARDs, alone and in combination, in methotrexate- and biologic-naive adults with moderate to severe early rheumatoid arthritis (ERA; <3-year duration). **METHODS:** Literature review identified randomized controlled trials (RCTs) of tDMARDs and novel DMARDs reporting efficacy outcomes (American College of Rheumatology [ACR] 20/50/70/90 response and Disease Activity Score at 28 joints [DAS28] remission). Data were pooled using Bayesian network meta-analysis techniques. For ACR response, data were analyzed using a fixed-effects ordered probit model, which makes efficient use of ordered categorical data and guarantees coherent prediction of multinomial response probabilities. For DAS28 remission, data were analyzed with a fixed-effects binomial logit model. Sensitivity analyses tested the effects of grouping treatments by class and broadening/narrowing inclusion criteria. **RESULTS:** Results from a synthesis of 16 RCTs of tDMARDs (methotrexate, sulfasalazine, hydroxychloroquine) and novel DMARDs (biologics [abatacept, adalimumab, etanercept, infliximab, golimumab, tocilizumab] and tofacitinib) indicated that biologics+methotrexate, triple tDMARDs, and tocilizumab and tofacitinib monotherapy significantly increased response across all ACR categories versus methotrexate. ACR response probabilities for biologics+methotrexate were not significantly different between agents. ACR response probabilities to novel DMARD monotherapy varied, trending toward higher values for tofacitinib and tocilizumab than etanercept or adalimumab. In studies reporting DAS28 remission, treatment with tofacitinib or biologics±methotrexate, except adalimumab alone, improved remission likelihood versus methotrexate. Tocilizumab±methotrexate generated the highest probability of remission among biologics and was significantly more effective than other biologics±methotrexate and tofacitinib. Results across outcomes were robust to alternative grouping of interventions and change in inclusion criteria. **CONCLUSIONS:** Based on ACR response, the expected efficacy of biologics+methotrexate, tofacitinib and tocilizumab monotherapy, and triple tDMARD therapy appeared higher than MTX in ERA. Tocilizumab±methotrexate was expected to have the highest probability of generating DAS28 remission and was significantly more effective than other biologics±methotrexate and tofacitinib.

### PMS11

### USING HEALTH ASSESSMENT QUESTIONNAIRE – DISABILITY INDEX TO ESTIMATE EQ-5D UTILITY VALUES FOR PATIENTS WITH RHEUMATOID ARTHRITIS IN TAIWAN

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**OBJECTIVES:** This study aims to provide estimates of EQ-5D as a function of Health Assessment Questionnaire – Disability Index (HAQ-DI) scores in patients with rheumatoid arthritis (RA) in Taiwan. **METHODS:** Face-to-face patient interviews on a total of 140 patients aged between 30 and 70 years old were recruited at the rheumatology outpatient clinics of four hospitals located in northern, central and southern Taiwan during June 2013-May 2014. The severity distribution of patients was mild RA (Disease Activity Score [DAS 28] <3.2) (N=57), moderate RA (3.2□…DAS<5.1) (N=44), and severe RA (DAS≥a5.1) (N=39). Socio-demographic and clinical information were collected, and the HAQ-DI and the EQ-5D questionnaires were completed. Generalized linear regression models were used to predict EQ-5D utility values as functions of HAQ-DI scores, age, and gender. **RESULTS:** Patient mean age was 50.8 years old (standard deviation [SD], 11.3 years); 81.4% of the patients were women and mean disease duration was 9.65 years (SD, 6.84 years). HAQ-DI <0.5, 58%; 0.5□…HAQ-DI<1.1, 16%; 1.1□…HAQ-DI<1.6, 9%, 1.6□… HAQ-DI<2.1, 12%; and HAQ-DI≥a2.1, 4%. HAQ-DI and EQ-5D mean scores were 12.01 (SD, 7.8) and 0.67 (SD, 0.34), respectively. The models were able to predict actual EQ-5D across the range of the HAQ DI. Age and gender were found to be significant determinants in estimating the utility functions. **CONCLUSIONS:** Utility values have very often not been assessed in the data collection process in a clinical trial. This study showed that HAQ-DI scores can be used to derive EQ-5D utility values for patients with RA in Taiwan to facilitate conducting a cost-utility analysis.

### PMS12

### HEAL RATE IN 4,190 FRESH FRACTURES TREATED WITH LOW-INTENSITY PULSED ULTRASOUND (LIPUS)

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**OBJECTIVES:** Patient age is one of many potential risk factors for fracture nonunion. We evaluate impact of age on heal rate (HR) in patients with fresh fracture (≤90 days old). Our hypothesis is that age is not a risk factor for nonunion if fractures are treated with LIPUS. **METHODS:** A LIPUS device was approved in 1994 to accelerate fresh fracture healing, though the FDA required a Post-Market Registry. Patient data were collected from October 1994 until October 1998 and were reviewed and

validated by a registered nurse. We required 4 data elements to report a patient: date when fracture occurred; date when treatment began; date when treatment ended; and outcome (healed vs. failed, by clinical and radiological criteria). Data were used to calculate: days to treatment (DTT); and days on treatment (DOT). All fresh fractures with DTT, DOT, and outcome are reported. **RESULTS:** 5,765 patients in the registry had fresh fracture; 73% of patients (N=4,190) are reported; 13% of patients were lost to follow-up; 11% withdrew or were noncompliant; and 3% died or are missing outcome. Among compliant patients, HR was 96.2%. Logistic estimates of the odds ratio for healing are equivalent for patients aged 30 to 79 years. Nevertheless, patients who failed treatment were 4.5 years older than patients who healed ($p < 0.0009$). DTT was significantly shorter for patients who healed ($p < 0.0001$). Data show that obesity, smoking, diabetes, vascular insufficiency, osteoporosis, cancer, rheumatoid arthritis, and chronic use of NSAIDs reduce HR. **CONCLUSIONS:** LIPUS mitigates the effect of age on fracture HR. Patients who used LIPUS had a 96% HR, whereas the expected HR averages 93%. Time to treatment was significantly shorter among patients who healed ($p < 0.0001$), suggesting it is beneficial to begin treatment early. Comorbid conditions in conjunction with aging can reduce fracture HR.

### PMS13
### PAIN THERAPY FOR OSTEOARTHRITIS IN GERMANY: ANALYSIS OF SICKNESS FUND CLAIMS DATA

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**OBJECTIVES:** Using sickness fund claims data, we sought to determine osteoarthritis rate, drug compound class, pain therapy prevalence and type of medical specialists providing treatment. **METHODS:** A group of company health-sickness funds (approx. 2.1 million insured patients in 2010; 2.5 million insured patients in 2011) was used. Osteoarthritis was identified based on ICD-10 diagnoses (M16.0-9, M17.0-5, M17.9, M19.05, M19.25, M19.85, M19.95), then linked to prescriptions using the ATC codes: M01A (nonsteroidal anti-inflammatory drugs, NSAIDS), N02B (analgesics and antipyretics), and N02A (opioids). Furthermore, we determined which groups of medical specialists prescribed the drugs. **RESULTS:** Osteoarthritis was diagnosed in 7.8% (in 2010) and in 7.1% (in 2011) of patients. In one year, 65.4% of patients received a prescription for at least one drug from the analysed ATC codes: 81.4% of patients received at least one NSAID, 36.4% an analgesic and antipyretic, and 27.4% an opioid. For M01A, diclofenac (54%) was most frequently prescribed; the proportion of coxibs was 6%. For N02B, 99% of prescriptions were for metamizol; 1% for paracetamol. For N02A, most prescriptions were for tramadol (29%) or tilidin (28%). General practitioners most frequently prescribed these drugs (42.2% [M01A]/46.2% [N02B]/45.9% [N02A]). **CONCLUSIONS:** In Germany in 2010-2011, OA prevalence was 7-8%, and associated with analgesic prescriptions for the majority of evaluated patients. Diclofenac (NSAIDs, metamizol (analgesics and antipyretics), and tramadol or tilidin (opioids) were most frequently prescribed in each group. General practitioners were the most frequent painkiller prescribers.

## MUSCULAR-SKELETAL DISORDERS – Cost Studies

### PMS14
### A BUDGET IMPACT ANALYSIS OF USTEKINUMAB IN THE MANAGEMENT OF PSORIATIC ARTHRITIS IN GREECE

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**OBJECTIVES:** Ustekinumab was approved for the treatment of psoriatic arthritis (PsA) in September 2013. The objective of the study was to estimate the budget impact of ustekinumab in the management of PsA in Greece. **METHODS:** A budget impact model was developed in Excel 2010 comparing the total PsA treatment costs in the current treatment pathway (including golimumab, adalimumab, etanercept and infliximab) with the respective costs of a treatment mix with the inclusion of ustekinumab. Market share data for the current treatment pathway were based on market research. Epidemiology data were taken from the published literature. Due to lack of published data on resource use, a 60-field questionnaire was developed in order to collect local data relating to the management of PsA in Greece. Two expert panels were convened, one with 8 KOL dermatologists and one with 8 KOL rheumatologists, with the Delphi technique. Unit costs were retrieved from publically available sources. The time horizon was five years and the analysis was conducted from the Social Insurance Fund perspective. **RESULTS:** The total number of eligible patients (incident and prevalent cases) was estimated to increase from 6,448 in Year 1 to 7,754 in Year 5. The total cost in the current treatment pathway was estimated to range between €48.4 million in Year 1 and €20 million in Year 5. The costs in the treatment pathway including ustekinumab were €47.8 and €18.5 million, in the respective years. Therefore, the addition of ustekinumab in the treatment mix can lead to cumulative savings for the Social Insurance Funds of €7.7 million, over the 5-year time horizon. This cost reduction is mainly attributed to the less frequent administration of ustekinumab. **CONCLUSIONS:** Inclusion of ustekinumab in the treatment mix appears to be a cost saving treatment option in the management of PsA in Greece.

### PMS15
### BUDGET IMPACT ANALYSIS OF CERTOLIZUMAB PEGOL IN THE MANAGEMENT OF PATIENTS WITH MODERATE-TO-SEVERE ACTIVE RHEUMATOID ARTHRITIS IN GREECE

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**OBJECTIVES:** To investigate the budgetary impact of increasing the patient share of certolizumab pegol (CZP) versus the other recommended biologic disease modifying anti-rheumatic drugs (bDMARDs; etanercept, adalimumab, golimumab, infliximab, abatacept, tocilizumab) for the treatment of moderate-to-severe active rheumatoid arthritis (RA) in Greece. **METHODS:** A budget impact model was adapted from a third-party payer perspective (National Organization for Healthcare Services Provision [EOPYY]) to evaluate economic aspects of RA treatment over 5 years (2014–2018). The model assumed Greek epidemiological data and local reimbursement requirements. Two main scenarios, following either a conservative or an increased market uptake of CZP in the Greek health care market, were estimated and individually compared to the current market trend scenario, which incorporates original biologics erosion from biosimilars entry in the coming year. Costs pertaining to drug acquisition, administration (only for intravenous drugs), and monitoring were included in the analysis and corresponded to 2014 costing year. Officially published sources were used to derive unit costs. The outcome measures were the annual cost of treatment with bDMARD presented as total cost and disaggregated by drug cost, administration cost and monitoring cost, as well as the incremental cost savings per year. **RESULTS:** Comparing CZP current versus conservative market uptake scenarios, the total budget was slightly increased by €0.05 million. In contrast, comparing CZP current versus increased market uptake scenarios, the total budgetary savings were €0.23 million. In the latter comparison setting, the cost savings were attributed to reduced drug and administration costs. More specifically, the greater replacement of an intravenously administered bDMARD (infliximab) conduced to the greater reduction of administration costs than in the former comparison setting (cost savings: €0.17 vs. €0.14 million). **CONCLUSIONS:** A potential increased use of CZP treatment was shown to be associated with cost savings over the next 5 years in Greece.

### PMS16
### PHARMACOECONOMIC EVALUATION OF BIOLOGIC THERAPIES IN RUSSIAN PATIENTS WITH RHEUMATOID ARTHRITIS AND INTOLERANCE OR INADEQUATE RESPONSE TO CONVENTIONAL BASIC THERAP

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**OBJECTIVES:** About 2.79% of patientswith rheumatoid arthritis (RA) in Russia receive TNF-α inhibitors; this value may vary significantly and depends on limitations of regional budgets. In this respect, the aim of our study was to conduct a comparative pharmacoeconomic analysis of the most prevalent TNF-α inhibitors in Russian patients with rheumatoid arthritis and intolerance or inadequate response to conventional basic therapy. **METHODS:** An pharmacoeconomic model was developed based on the data from indirect comparison of anti-TNF-α agents. The model considers the use of infliximab, etanercept, certulizumab pegol, adalimumab in patients with RA who lost response to conventional basic therapy. Cost-effectiveness and costs of TNF-α inhibitors for health care budget were estimated. The cost analysis included costs of pharmacotherapy. Infliximab and etanercept are included into the list of vital and essential medicines and were considered as accepted technologies in budget impact analysis: certulizumab pegol and adalimumab were novel tecnologies in our model. A 24-weeks horizon was adopted. Sensitivity analysis (SA) was performed by changing costs of medicines **RESULTS:** the costs of therapy in certulizumab pegol and etanercept groups were significantly lower than in infliximab and adalimumab groups. The cost-effectiveness ratios (CERs) in terms of ACR20 in 24 weeks were 703 625.00, 587 776.09, and 4 119 260.82 for certulizumab pegol, etanercept and infliximab groups, respectively. The same was observed in case of ACR50 and ACR70: a strategy of drug use in certulizumab pegol and etanercept groups was preferable in comparison with infliximab and adalimumab groups. Budgetary costs for health care system were higher in case of infliximab and adalimumab. SA confirmed the robustness of the model **CONCLUSIONS:** The study demonstrated that certulizumab pegol and etanercept are an economically effective strategy for Russian patients with RA and lost response to conventional basic therapy.

### PMS17
### MAST (MINIMAL ACCESS SPINAL TECHNOLOGIES) VERSUS OPEN SURGERY: COST ANALYSIS FROM HOSPITAL PERSPECTIVE

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**OBJECTIVES:** The objective of this study was to determine and compare the resource consumption associated with open vs. minimal invasive surgery in patients with degenerative spinal disorders in the Russian hospital setting. **METHODS:** Conducted cost-analysis was based on Moscow hospital setting, where resource utilization associated with average one-level spinal operation was determined through interviews with KOLs in spinal surgery. Costs were retrieved from public sources and hospital data for the following categories 1) hospital stay; 2) blood transfusion 3) consumables (suture materials, hemostatic sponges, disposable instruments); 4) time in the operating room; 5) spinal implants/instrumentation; and 6) complications. **RESULTS:** The results of the calculations have confirmed MAST economic advantages over open surgery (OS). MAST was associated with fewer costs, mainly due to shorter stay in intensive care unit (1 vs. 2 days) and general ward (9 vs. 15 days), no need for blood transfusion and less rate of complications. The difference in the duration of surgery, which depends mainly on the speed of approach and the installation of implantable structures, is approximately 20 minutes in favor of MAST. With the cost of one-hour long surgery at about 6,000 rubles (167$), excluding the cost of implantable structures, the use of MAST instead of OS translates into savings of 2,000 rubles (56$) per each surgical intervention. As for overall budget savings, the use of MAST translates into savings of between 14,783 ($410) and 35,000 ($970) rubles per whole hospital visit, depending on what materials and structures are used. **CONCLUSIONS:** The economic evaluation confirms economic domination of MAST over OS. Despite initial higher investments, MAST appears to be a cost saving alternative to OS, in terms of diminution of actual surgery time, reduction of blood transfusion costs, and prevention of post-surgery complications and shorter overall length of hospital stay.